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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GODBey GRIFFITHS REISS
1001 BISHOP STREET
2300 PAUAHI TOWER
HONOLULU, HI 96813

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/596,362

Applicant(s)

STEINER, GREGORY

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 02/18/04. Claims 1-6 and 10-16 are pending. Applicant indicated in the remarks that copy of article reference by Coffey et al., "*Trauma and substance cue reactivity in individuals with comorbid posttraumatic stress disorder and cocaine or alcohol dependence*," Science Direct, Vol. 65, Issue 2, January 1, 2002, pages 115-127 was enclosed with the amendment and remarks. However, this reference is not available in the file. A search in the Science Direct Database reveals that the Coffey article was published in the Drug and Alcohol Dependence Journal. It appears from the abstract of said article from the Medline file that the article is reporting on posttraumatic stress disorder related negative emotion between the two types of abuse, namely crack cocaine dependence and alcohol dependence and suggests that posttraumatic stress disorder may play relatively more important role in the maintenance of alcohol dependence when compared to crack cocaine dependence; it is not immediately clear how as per applicant, the physiological and psychological underpinnings of craving for the two substances differ in the alcohol abuse cases and the crack cocaine abuse cases and how it related the use of tetrahydropyranone (pyrone) for treating alcohol and other drug dependence and for that matter the treatment of cancer.

Regarding the issue about the cited prior art not recognizing or appreciating that "kava kava was capable of functioning as an anti-depressive and anti-anxiety agent in the treatment of recovering alcoholics," it is respectfully noted that the effect of the kava kava on a subject or any subject would be inherent in the property or attributes of the kava kava. It is noted that the property or attribute inherent in the kava kava cannot be separated from the kava kava. Also, when the claim recites using an old composition or structure and the "use" is directed to a result

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or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). See also In re Tomlinson, 363 F.2d 928, 150 USPQ 623 (CCPA 1966). Discovery of new use for an old product/composition is finding a property in the old composition/product (363 F.2d at 934, 150 USPQ at 628 (emphasis in original)).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 1-6 and 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 directs the reader to structural formula of alpha pyrone and defines R1, R2 and R3 without giving the structure of the pyrone. Examiner suggests to applicant to please provide the structure of the pyrone in claim 1 to enable one to understand the structure without referring back to the disclosure for the structure.

Claims 3-6 directed to the form in which the composition of claim 1 is to be administered appears not to further limit the method claim. Specifically, the claims are vague because the claims are confusing since the method of treating alcohol craving does not comprise a pill, gum, transdermal patch or liquid. However, for examination purposes, the claims are interpreted as method of claim 1 wherein the anticraving composition of matter is administered in the form of a pill, gum, transdermal patch or a liquid.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, 6, 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cherksey (US 5,234,947).

Cherksey discloses a method of alleviating symptoms of tobacco addiction withdrawal or nicotine addiction withdrawal by administering to a subject a composition having an effective amount of a pyrone, an alpha pyrone derived from kava root or piper methysticin Forst, the Polynesian kava kava plant (abstract, columns 5 and 6 and claims 1-5). In Cherksey, when R is methoxy (alkoxy) or C1-C4 unsaturated or saturated moiety, and R' is hydrogen or lower alkyl (C1-C8) or lower alkenyl or aralkyl (column 4, lines 28-44 and claims 1 and 3) corresponds to the instant pyrone. R1 and R3 of the instant pyrone correspond to R and R' of Cherksey and R2=hydrogen in the instant claim corresponds to the hydrogen on the carbon atom between R and R' in Cherksey. In addition to treating withdrawal symptoms from nicotine or cigarette addiction, Cherksey also discloses that the pyrone compounds may be used to treat alcohol or narcotic addiction (column 4, lines 46-57). The pharmaceutically acceptable compositions comprise pharmaceutical excipients and carriers (column 7, lines 28-62 and column 8, lines 4-33) and the compositions are formulated and administered orally as tablets, dragees and capsules; the formulation can also be rectally administered as suppositories; the formulation can also be administered orally and by injection as solutions (liquid); and the formulation can be parenterally administered as oily injection suspension (column 7, lines 19-51; column 8, lines 34-36).

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In the background section, Cherksey discloses that kava kava has been traditionally prepared and made into tea in the Polynesian islands and that the kava kava root is chewed (column 2, lines 31-64). Tea is a beverage.

The pyrones are extracted using organic solvents and a strong spirit is made from the juice of berries (column 5, lines 1-51 and column 2, lines 51-58). Claims 14-16 are treated as the composition claim of 13 that contains a pyrone as claim 13. How a composition is formulated is not accorded patentable weight and what is required is for the prior composition to have the necessary and component parts. The properties of a composition are inherent and cannot be separated from the composition. The taste parameters recited in claims 14-16 are inherent properties of the kava kava.

Cherksey meets the limitations of the claims.

5. Claims 1-2 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Umbdenstock (US 5,332,579).

Applicant argues that Umbdenstock discloses a method of treating substance abuse related cravings with a broad range of vitamins and mineral and optionally the composition contains herbs including kava kava and that Umbdenstock failed to appreciate that kava kava was capable of functioning anti-depressive and anti-anxiety agent in the treatment of recovering alcoholics.

6. Applicant's arguments filed 02/18/04 have been fully considered but they are not persuasive.

The method administers a composition that contains a kava product and the prior art administers a composition that contains a kava product. The prior art discloses treating

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individuals recovering from alcohol addiction. It would be inherent that the prior art composition has the function that is associated with the property of the kava kava. And something, which is old, does not become patentable upon the discovery of a new property.

“[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 and MPEP § 2141.02.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherksey (US 5,234,947).

Cherksey discloses the method and composition of the instant claims. Cherksey does not disclose treating nicotine addiction by transdermally administering the pyrone containing composition to a subject. Regarding administering the composition as gum, it is noted that Cherksey discloses that the kava containing composition can be chewed and as such formulating the formulation of Cherksey would be an obvious variation of the dosage form. It would have been obvious to one of ordinary skill in that art at the time the invention was made to administer the pyrone containing composition as capsule or tablet. One having ordinary skill in the art

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would have been motivated to administer the composition of Cherksey as a transdermal patch for treating nicotine with the expectation of facilitation of the absorption of the drug, which in turn would facilitate smoking cessation (see Houdi in US 6,121,289 as a teaching reference).

9. Claims 3-6 and 13-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Umbdenstock (US 5,332,579).

Applicant argues that Umbdenstock teaches away from the claimed invention and Cody discloses that Piper methysticum containing composition diminishes the desire for tobacco, which does not represent treatment for alcoholism. Applicants stated that the claimed invention was reduced to practice before December 12, 1997.

10. Applicant's arguments filed 02/18/04 have been fully considered but they are not persuasive.

Umbdenstock does not teach away from the claimed invention because Umbdenstock discloses nutritional supplement containing kava kava to treat alcohol addiction. Cody as admitted by applicant discloses that kava kava containing composition diminishes the desire for tobacco, which will invariable assist one that is dependent on tobacco/nicotine to cease from using. Regarding applicants reduction practice in December of 1997, it is noted that there is no data or evidence that such is the case.

11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

